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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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08/978,634

11/25/1997

ELAZAR RABBANI

ENZ-53(DIV-2

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12/30/2008

ENZO BIOCHEM, INC.

527 MADISON AVENUE (9TH FLOOR)

NEW YORK, NY 10022

EXAMINER

SHIN, DANA H

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

12/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 08/978,634 | Applicant(s) RABBANI ET AL. | |
| | Examiner DANA SHIN | Art Unit 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 275,289,290 and 296-301 is/are pending in the application.
- 4a) Of the above claim(s) 289,290 and 298-301 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 275,296 and 297 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11-29-2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 28, 2008 has been entered.

Status of Claims

Claims 275, 289-290, and 296-301 are currently pending in the instant application. Claims 289-290 and 298-301 have previously been withdrawn as being drawn to non-elected inventions. See applicant's election with traverse filed on March 2, 2008. Accordingly, claims 275 and 296-297 are currently under examination on the merits in the instant case.

Response to Arguments

Applicant's arguments filed with the RCE, with respect to the rejection(s) of claim(s) 275 and 296-297 under 35 U.S.C. 112, first paragraph and 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection are made. See below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 275 and 296 are rejected under 35 U.S.C. 102(b) as being anticipated by Engelhardt et al. (US 5,260,433, applicant's citation).

The claims are drawn to a multimeric composition comprising more than one monomeric unit, wherein each monomeric unit comprises a protein ligand to a cell surface receptor and a single-stranded polynucleotide, wherein the single-stranded polynucleotide is attached via hydrogen bonding to a complementary single-stranded polynucleotide, wherein the cell surface receptor is a hormone receptor or the ligand is a hormone.

Engelhardt et al. teach a multimeric composition comprising multiple protein ligands covalently attached or bound to a single-stranded polynucleotide or a double-stranded polynucleotide of A:U comprising a single-stranded poly A nucleotide and a single-stranded poly U nucleotide, wherein the protein ligands bind to their cognate protein receptors such as hormone receptors. See columns 26-28. Accordingly, all claim limitations are taught by Engelhardt et al.

Claim 275 is rejected under 35 U.S.C. 102(b) as being anticipated by Myers (EP 0273085 A1, applicant's citation).

The claim is described above.

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Myers teaches a multimeric compound comprising a double-stranded polynucleotide attached to EGF molecules, wherein the double-stranded polynucleotide comprises two independent complementary single-stranded polynucleotides. See the entire reference. Hence, all claim limitations are taught by Myers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 275 and 296-297 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelhardt et al. (US 5,260,433, applicant's citation) in view of Osborne et al. (*PNAS*, 1976, 73:4536-4540).

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The claims are drawn to a multimeric composition comprising more than one monomeric unit, wherein each monomeric unit comprises a protein ligand to a cell surface receptor and a single-stranded polynucleotide, wherein the single-stranded polynucleotide is attached via hydrogen bonding to a complementary single-stranded polynucleotide, wherein the cell surface receptor is an insulin receptor or the ligand is insulin.

Engelhardt et al. teach a multimeric composition comprising multiple protein ligands covalently attached or bound to a single-stranded polynucleotide or a double-stranded polynucleotide of A:U comprising a single-stranded poly A nucleotide and a single-stranded poly U nucleotide, wherein the protein ligands bind to their cognate protein receptors such as hormone receptors. See columns 26-28. Engelhardt et al. do not teach that the hormone receptor is insulin receptor or that the hormone ligand is insulin.

Osborne et al. teach that insulin, glucocorticoids, prolactin, and estrogen are hormones and that insulin interacts specifically with its receptor, insulin receptor, to simulate growth in human breast cancer cell lines. See the entire reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have insulin in place of the generic protein hormone ligands of Engelhardt et al.

One of ordinary skill in the art would have been motivated to do so because only countable number of protein hormone ligand species were known in the art including insulin at the time of the invention as taught by Osborne et al., and because the structure of a multimeric compounds comprising two complementary polynucleotides to which protein hormone ligands are covalently attached was known in the art as taught by Engelhardt et al. Hence, the ordinary skilled artisan would have had made, with a reasonable expectation of success, a multimeric

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composition comprising multiple insulin ligands covalently attached to a double-stranded polynucleotide at the time of the invention. Accordingly, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635